Direct Healthcare Services

Delivering the Promise

Dyna-Form®
Air Suresse

User Manual

The **Dyna-Form® Air Suresse** is the latest high dependency, dynamic mattress replacement system within the DHS range of products. This product is manufactured with a dual compressor system, allowing suitable application to those much larger, complex patients and a 40 stone / 254kg weight limit as standard. This modern pump technology also comes equipped with a true fault diagnostic system, providing potential, rapid minor problem diagnosis and therefore real peace of mind.

The “Soft to Firm” selection functions allow true patient comfort, from the light weight, hypersensitive, to those heavier patients, up to and including and that of Very High Risk of pressure ulcer development and existing damage. This new and unique hinged mattress cell construction provides small and deeper cell designs for the heel and sacral areas, allowing for use on the most challenging patient circumstances and most healthcare beds. At ease within any high dependency ward to that of a homecare setting, this multi disciplinary system assists with the modern challenges of pressure area patient care at the highest level.

Dyna-Form® Air Suresse

Important Notice

Before operating this medical equipment, it is important to read this manual and understand the operating instructions and safety precautions. Failure to do so could result in patient injury and/or damage to the product.

If you have any questions, please see contact information on cover.

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Dyna-Form® Air Suresse

This box contains an assembled mattress system containing a:

A. Dyna-Form® Air Suresse Alternating Mattress Replacement System

B. Digital Control Unit

C. Power Cord

D. Carry Bag

E. Instructions for Use

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1. Safety Precautions

In General

⚠ Do not use this equipment in the presence of flammable anaesthetics. Explosions could result. In line with MDA/2013/073 the manufacturer warns against the dangers of smoking in bed.

⚠ Bed frames used with the systems can vary greatly depending on the specific health care setting (i.e. hospitals, nursing homes, home care, etc). It is the responsibility of the caregiver to take the necessary precautions to ensure the safety of the patient. This includes, but is not limited to, the appropriate use of side rails to prevent falls and/or patient entrapment.

⚠ Minimize articles between the system surface and patient, and secure bed sheets loosely so as not to affect the alternating cell movement.

⚠ The manufacturer does not require such preventive inspections by other persons.

⚠ The user must check that the equipment functions safely and see that it is in proper working condition before being used.

⚠ No special skills or training of the operator is required, there is no restriction on location or environment.

⚠ Significant risks of reciprocal interference may be posed by the presence of the system during specific investigations or treatments. Potential electromagnetic or other interference between the system and other device may occur. If interference is suspected, move equipment from sensitive devices or contact the manufacturer.

⚠ Preventive inspection and calibration is not required.

⚠ Do not modify this equipment without authorization of the manufacturer.

⚠ Manufacturer will provide circuit diagrams, component part lists, descriptions to assist to service personnel in parts repair.

⚠ The mattress is treated as the applied part.

⚠ Unplug the control unit from the mains power supply to disconnect the power.

Control Unit

⚠ The control unit is tested and approved according to ISO-EN 60601-1 rev.2 & EMC

⚠ Only plug into a grounded power receptacle and use the power cord supplied with the system.

⚠ Exposure of the electronic Control Unit to any liquid while it is plugged in could result in a severe electrical hazard.

⚠ Only use fuses that have the same specified rating. Using fuses with higher ratings could result in damage and/or injury. (See Technical Specifications on cover).

⚠ The electronic Control Unit is a precision electronic product. Use care when handling or transporting. Dropping or other sudden impacts may result in damage to the unit.

⚠ Do not open the Control Unit – risk of electrical shock. Do not attempt to repair or service the Control Unit. Repairs and service should be conducted by an authorised local distributor. (See contact information on cover). If the Control Unit is not functioning properly, or has been damaged, unplug the unit and take it out of service immediately. (See contact information on cover for repair and service information).

⚠ Do not place any objects or items, such as blankets, on or over the Control Unit.

⚠ The power cord to the Control Unit should be positioned to avoid a tripping hazard and/or damage to the cord. It is recommended to place the cord under the bed frame and attach it to an electrical outlet by the head of the bed.

⚠ Do not position the system so that it is difficult to operate the disconnection device.

2. Product Overview

Alternating Mattress system (see cover)

Dyna-Form Air Suresse is an Alternating Mattress Replacement System providing pressure application and release to patients with, or vulnerable to, pressure ulcers. It is designed to replace an existing mattress and can be used on both standard and profiling bed frames.

Mattress

This system includes a static head cell(s) to provide static "pillow" support for optimum user comfort, while air pressure in the other cells is alternated over a 12 minute cycle. This provides regular periods of pressure reduction to aid blood and lymphatic flow to vulnerable tissue.

Control unit

The Control unit provides the air supply to the Mattress.

- It is controlled via a touch panel with integrated digital display. The Audible Warning sounds when pressure fails or power is interrupted. Audible Warning Mute silences the Audible Warning for maximum of 20 minutes – the Audible Warning resumes if cause of failure is not resolved. The Audible Warning will sound for up to two hours following an interruption to power.
- The Control Unit includes a back up power battery for the Audible Warning. This battery is continuously re-charged and will last the lifetime of the product.
- Buttons on the control panel adjust the three comfort level settings.
- The Warning LED indicator and Audible Warning Mute completes the profile.

The visible and audible warning functions has a number of indicators depending on the cause of the failure.

The mains supply to the Control Unit can be easily disconnected and is designed to detach if tugged too firmly - protecting the internal wiring of the unit. Should this occur, the alternation sequence is suspended and the Mattress cells remain inflated and/or deflated based on the current cycle. The Power Down Audible Warning will sound. (See picture on front cover).

Installation

Unpacking & Inspection

⚠ It is recommended that all packing materials and instructions be kept in the carry bag provided in the event the product has to be shipped to Direct Healthcare or an authorised local Direct Healthcare distributor. Please see contact information on back cover.

Carefully remove the Control Unit, Mattress Replacement and accessories from the boxes. Inspect all items for any damage that may have occurred during shipping. Any damage or missing components should be reported to Direct Healthcare or an authorised local Direct Healthcare distributor as soon as possible. Please see contact information on cover.

3. Operation

Control Unit Panel (see front cover)

A Power Button

Turns system power on and off by pressing the Power button for at least two seconds.

B Warning LED *A,B & C

One of *these red light flashes, and an audible warning sounds, to alert when Control Unit or Mattress Replacement pressure fails. The warning has three different signals to indicate the cause of the failure (see over).

The Audible Warning also sounds when power is switched off – press Audible Warning Mute to silence.

C Audible Warning Mute Button

Silences the audible warning (on / off). Audible warning will resume after 20 minutes if cause of failure not resolved.

D Pressure Buttons (Soft, Medium & Firm)

Press buttons to increase or decrease pressure setting. The Soft, Medium & Firm settings allow comfort to the user, without clinical compromise. The green LEDs illuminate to indicate which of the three settings is operational.

E Dynamic Function Button

Press Dynamic Mode for alternative cells cyclically inflating and deflating.

Static Mode will automatically revert to Alternation Mode after one hour for patient safety.

Upon power up, the system automatically reverts back to the dynamic mode operating at the previous pressure setting for patient safety.

Static Mode will automatically revert to Alternation Mode after one hour for patient safety.

F Static Function Button

Press to facilitate static mode for clinical procedure / patient transfer purposes. After 20 minutes, the system automatically reverts back to the previous pressure setting for patient safety.

Press Static Mode for all cells to be fully inflated with no dynamic alternation.

Static Mode will automatically revert to Alternation Mode after one hour for patient safety.

G Control Unit Lock / Unlock Button

Press for at least two seconds to lock the Control Unit settings – a beep sounds and the amber LED illuminates to indicate system is locked. When locked, only the Audible Warning Mute and Lock / Unlock buttons remain operational.

Press again for at least two seconds to unlock (beep sounds and amber LED turns off).

⚠ The Control Unit will automatically unlock in the event of a power failure.

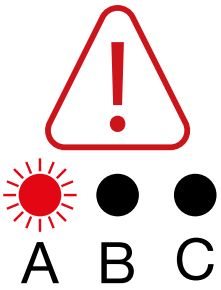
Operation

Warning Function

The red Warning LED (A,B or C) flashes, and an audible alert sounds, to indicate the control unit or mattress pressure has failed. The LED will remain illuminated until appropriate pressure is restored. The audible warning can be silenced by pressing the Audible Warning Mute button.

The system has three different warning signals, identified by illumination sequences.

The signals and corresponding Pressure Setting LED displays are illustrated below.



Display	Warning Signal	
	High pressure	The system cannot reach the set pressure within 8 minutes. The system pressure is too high.
	Low pressure	The system cannot reach the set pressure within 8 minutes. The system pressure is too low.
	Mains Failure	Power unit has no power feed.

Operation

Mattress Function

Establishing Pressure (supine patient)

With the patient lying supine (on their back, face upwards), select the soft, medium or firm setting based on patient weight and comfort requirements. You may also select the 'Dynamic' or 'Static' setting using the relevant buttons.

Before changing or lowering the pressure, ensure the system is working effectively by performing a 'bottoming out' test:

Bottoming Out Test

When altering the pressure setting, ensure the patient is not 'bottoming out' (insufficiently supported by the air cells and therefore coming in contact with bed base).

1. Ensure system is in alternation mode but is not undergoing an alternation.
2. With the patient lying in a supine position, unzip top cover just past sacral (bottom) region.
3. Slide your hand along a deflated cell under the patients sacral area (bottom). The inner static cell will remain inflated but your hand should slide easily between patient and base.
4. If a hand can pass under patient then the patient is adequately suspended and pressure can be lowered.
5. Repeat Bottoming Out test after pressure has been lowered.

In the event of a system malfunction, the Audible Warning will activate and pressure LEDs will flash.

Establishing Pressure (inclined patient)

When moving the patient to a sitting or more upright position, pressure may need to be increased to a medium or firm setting in order to provide added support and to avoid 'bottoming out'.

⚠ It is important to return to the original pressure setting when the patient returns to the supine position.

⚠ Wait a minimum of 12 minutes between pressure adjustment and patient assessment, as it may take a cycle for the system to adjust.

CPR Function

Rapid deflation of the Mattress may be required for emergency treatment or to decommission the system. Firmly pull the Rapid Release /CPR Tag from the side of the Mattress to rapidly deflate the entire system.

To re-inflate the system after the Rapid Release/CPR Tag has been removed replace as such, ensuring all sealing connectors are firmly attached and restart the Control Unit. Wait for the Mattress system to gain optimal pressure.

Perform a Bottoming Out test after inflating the mattress following rapid deflation.

Mattress replacement system

The Air Suresse is a replacement mattress system. Remove the standard / foam hospital mattress before patient use.

Operation

Transport Function

1. Before patient transport, switch modes from alternating to static and wait for 10 -15 minutes for cells to inflate to maximum pressure.
2. Turn off the Control Unit.
3. Remove the mattress connection from the Control Unit. Allow air to escape for a few seconds before sealing with the attached transport cap, see picture on cover. This will soften the Mattress surface for pressure relief and comfort. Air can be sealed in the system for 30 hours as a transport feature.

   If the patient is responsive, check comfort level based on current pressure and adjust accordingly.

⚠ Always perform a 'bottoming out' test (see page 8) to ensure the patient is adequately supported and not touching bed base.

System Removal

1. Turn off the Control Unit by pressing the Power button for at least two seconds and unplug the power cable.
2. Remove the Rapid Release Handle from the Control Unit.
3. Place Control Unit and power cable on top of the Mattress and detach Mattress from the bed frame.
4. Once air has been released from all cells, roll up the Mattress and return all items to Carry Bag for safe keeping.

⚠ Prior to re-starting the system, ensure the Rapid Release Handle is firmly connected to the Control Unit.

4. Troubleshooting

Warning/Fault	Cause	Solution
Control Unit does not operate; no display lights illuminate	The Control Unit may not be attached to a power source or a fuse may need replacing	1. Check the Control Unit is connected to mains power outlet with the correct voltage. 2. Check the Control Unit is switched on. Switch off and unplug the unit before restarting. 3. Check the mains plug fuse (3 AMP) then check both Control Unit fuses (1 AMP) – fuses can be released using a screwdriver to push and turn. ⚠ Do not try to open the Control Unit. Opening the unit could cause personal injury or equipment damage. ⚠ Ensure the replacement of fuses is carried out accordance with local legislation.
Warning LED C + audible warning 	Mains failure / Other (see above plus>)	1. Reset the warning -turn off power and press the audible warning mute button. 2. Check the handle is intact, ensuring all four sealing connectors are firmly fitted to the control unit and the air hoses. Check the CPR tag is attached and all sealing connectors are firmly secure. 3. Check all air hoses along the inside of the mattress -each should be firmly connected. Check each air cell is securely attached to its connecting air pipe. 4. Check all cells, pipes and hoses for any air leakage. 5. Switch on power.
Warning LED B + audible warning 	Pressure too low	1. Reset the warning -turn off power and press the audible warning mute button. 2. Check the handle is intact, ensuring all four sealing connectors are firmly fitted to the control unit and the air hoses. Check the CPR tag is attached and all sealing connectors are firmly secure. 3. Check all air hoses along the inside of the mattress -each should be firmly connected. Check each air cell is securely attached to its connecting air pipe. 4. Check all cells, pipes and hoses for any air leakage. 5. Check that the air filter cover is correctly secured and the air filter is clean. 6. Switch on power.

Troubleshooting

Warning/Fault	Cause	Solution
Warning LED A + audible warning 	Pressure too high	1. Reset the warning -turn off power and press the audible warning mute button. 2. Disconnect the air hoses to reduce pressure - reconnect when pressure has decreased. 3. Check for twists in the air hoses between Mattress and Control Unit. 4. Switch on power.
Other checks to consider as below:		
Warning LED Any + audible warning	Alternating Mode Failure (no alternation)	1. Reset the warning – turn off Power and press the audible warning mute button. 2. Disconnect the air hoses to reduce pressure – reconnect when pressure has decreased.
Warning LED Any + audible warning	Power down	1. Press the audible warning mute button to silence the audible warning. 2. Check the power cable is firmly plugged into the mains outlet and the Control Unit; and check the mains power is switched on. 3. Check the Control Unit fuse (1 AMP) – fuses can be released using a screwdriver to push and turn.
Patient is sinking or “bottoming out” whilst lying flat on the Mattress Replacement	The pressure may be set too low for the patient’s weight	1. Increase the pressure setting by pressing up the Pressure arrow. 2. To check effective system performance, conduct a “bottoming out” test as described on page 8. ⚠ If the problem is not resolved, please contact Direct Healthcare or an authorised local distributor. See contact information on cover.

5. Cleaning

Before the cleaning and disinfection procedure, please use hygienic hand disinfection with an alcoholic skin disinfectant.

To protect clothing, use plastic apron, face mask and gloves.

Infection Control and routine cleaning must be carried out in accordance with your local Infection Control Policy. It is suggested that all disinfection be done with a high grade disinfectant in accordance with manufacturer's instructions.

⚠ Use authorised cleaning and disinfection solutions only!

⚠ The working table and the system must be cleaned and disinfected.

⚠ Concentration and exposure time of the solutions must be noted!

⚠ The top cover seams are sealed to prevent moisture ingress and bacterial growth in the seam stitching.

⚠ Do not use high temperature autoclave, or use Phenolic based products for cleaning.

⚠ It is recommended the system is cleaned between patients and approximately every two weeks if in constant use.

⚠ Refer to the cleaning and disinfection information for the Air Suresse system for additional guidance.

⚠ In case of questions in hygiene please contact an authorised local Direct Healthcare distributor.

Mattress Base

Wipe down the outside shell with authorised cleaning and disinfection solutions, ensuring that all surfaces come in contact with the disinfectant. Rinse off well with a clean damp cloth and air dry. Should Air Cells require disinfecting, disconnect.

Air Cells from the base by unfastening the press studs at each end and disconnecting air pipes from main air hoses before sliding each cell out from the cell straps. Swab with authorised cleaning and disinfection solutions. Dry thoroughly with a soft cloth before refastening.

⚠ Do not machine wash or dry the Air Cells or Mattress base.

⚠ Do not disassemble the Mattress unless cleaning is required. If cleaning or disinfecting is required, do not disconnect the pipes from individual Air Cells.

Cleaning

Top Cover

⚠ Refer to the top cover wash tag for cleaning instructions.

If there are visible signs of body fluids and or substances present, the top cover should be washed. Top covers can be machine washed (up to 80ºC) using authorised cleaning and disinfection solutions.

To establish the amount of disinfectant to use, determine the amount of water in the washer and then follow the manufacturers' instructions for dilution.

Soak the top cover in the disinfectant during the wash cycle. Rinse well in clean water and dry thoroughly before use.

⚠ Do not dry the top cover using too high a heat cycle (see Dartex technical recommendations - up to 80ºC). Air dry if possible or select an appropriate heat dry cycle within limits as above. If there are no visible signs of body fluids and or substances on the top cover, the top cover should be sanitized and rinsed with fresh water accordingly.

If there are no visible signs of body fluids and or substances on the top cover, the top cover should be sanitized.

1. Apply an intermediate level authorised cleaning and disinfection solution to the top cover upper surface either by spraying or by hand application.
2. Ensure the surface is completely covered with the disinfectant and remains in contact with the surface according to manufacturer's instructions.
3. Remove disinfectant and rinse thoroughly.
4. Allow to air dry before use.

Handle

The exterior of the Handle can be periodically wiped using a cloth and dampened with authorised cleaning and disinfection solutions.

Control Unit

⚠ Ensure the Control Unit is disconnected from the mains electricity supply before cleaning.

⚠ Do not spray disinfectant directly on to the Control Unit, or immerse the Control Unit in any type of liquid. This could result in a severe electrical hazard as this equipment has no protection against ingress of water.

⚠ This equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

Wipe down Control Unit with warm water containing detergent (or authorised cleaning and disinfection solution) and dry thoroughly before use.

⚠ In case of notifiable diseases clean and disinfect systems following eventually special procedures revised and published by the local health care authorities. The transport should take place in special plastic bags only.

6. Maintenance

Air Filter Replacement

1. Switch off the power supply to the Control Unit.
2. Disconnect the power lead and air hoses.
3. Place the Control unit on a flat surface with back panel uppermost (place soft cloth under unit to prevent scratches).
4. Carefully remove air filter cover, remove and discard the filter material and fit new filter (there may be a small locking screw – use a small Phillips head screwdriver to remove).
5. Refit the air filter cover to the Control unit. The Control unit is now ready for re-connection.

⚠ Good filter maintenance is critical to maintain your system in optimal operating condition. Failure to keep the filters clean will result in system downtime and increase repair costs. It is recommended that the air filter be replaced annually. Replacement air filters are available from an authorised local Direct Healthcare distributor. Please see contact information on cover.

Fuse Replacement

1. Switch off the power supply to the Control Unit.
2. Remove the power cord from the electrical socket on the side of the base of the Control Unit.
3. Insert a small Flat head screwdriver into the groove and turn anti-clockwise (quarter turn).
4. Remove the “blown” fuse from the fuse holder clip and discard.
5. Insert a new fuse into the plug. Push against the force of the spring and turn clockwise with the screwdriver (quarter turn).

⚠ Ensure the replacement of fuses is carried out accordance with local legislation.

7. Warranty Information

This product is produced to perform in accordance with established specifications, starting from the date the product is shipped.

The warranty period is two years.

During the warranty period repairs and replacement will be made on products that are not performing in accordance with established specifications, unless the problem/failure is due to:

- customer damage, negligence and/or misuse.
- unauthorised repairs.

Items not covered under warranty include, but are not limited to, stains, punctures, cuts, damages to electrical cords, rips or tears, dents and/or lost/missing parts.

Neither the company (see contact information on back cover), its distributors, officers, directors, employees or agents shall be liable for consequential or other damages, including but not limited to personal injury, loss, or any other expense, directly or indirectly arising from the use of its products. The sole remedy for breach of the limited warranty granted herein shall be repair or replacement of the products.

If you have any questions see contact information on back cover.

8. Technical Specification

Definition of Symbols Used

The following symbols may appear in this manual, on the Control Unit, or on its accessories. Some of the symbols represent standards and compliances associated with the Control Unit and its use.

Caution: Consult accompanying documents

Class II equipment

Manufacturer

SN Serial number

Type B applied part

DISPOSAL: Do not dispose of this product as unsorted municipal waste.
Collection of such waste separately for special treatment is necessary.

Operating Instruction

Keep Dry

Technical Specification

Declaration – electromagnetic emissions - for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emission The MAT/SURESSE/PUMP is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Technical Specification

Declaration – electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity The MAT/SURESSE/PUMP is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	±1kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Span system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Technical Specification

Declaration – electromagnetic immunity – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity

The MAT/SURESSE/PUMP is intended for use in the electromagnetic environment specified below.

The customer or the user of the system should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000- 4-6	3 Vr_{ms} 150 kHz to 80 MHz	3 Vr_{ms}	Portable and mobile RF communications equipment should be used no closer to any part of the CT515, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter Recommended separation distance $d = 1.167\sqrt{P}$ $d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Span system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.

b. Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

Technical Specification

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for ME EQUIPMENT or ME SYSTEM that are not LIFE - SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the MAT/SURESSE/PUMP Alternating Control Unit

The MAT/SURESSE/PUMP is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 KHz to 80 MHz $d = 1.167\sqrt{P}$	80 MHz to 800 MHz $d = 1.167\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.333\sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Technical Data

Power Unit (Pump)

Serial Number ..... As per label on rear of pump
Electrical Supply. ..... 220-240 volt, 50 Hz
Power Consumption ..... Max 20 watts
Fuses TA1H 250V
Protection against shock ..... Class 2
Noise Level ..... Approx. 30 dB (A)
Dimensions ..... 280 x 280 x 160 mm
Weight ..... 4.4 kg
Service Interval ..... 12 months
Expected life ..... 5 years
Shelf life of parts ..... 5 years

Mattress

Serial Number ..... Label on inside of mattress cover
Number of Air Cells ..... 19 cells & 2 lateral cells
Dimensions ..... 2000 x 850 x 250mm
Weight ..... 11 kg
Expected life of Mattress ..... 5 years
Shelf life of Mattress parts ..... 5 years

Optimum Conditions

(Applies to Mattress and Pump)

Environment Conditions for Use

Transport ..... -25˚C – +70˚C
Storage ..... -25˚C – +70˚C
Usage ..... +5˚C – +40˚C
Humidity ..... 10% – 93%
Atmospheric Pressure ..... 700hPa – 1060hPa
Operational Altitude ..... ≤ 2000m

Contraindications For Use (Warning)

The Suresse mattress should not be used for patients with unstable fractures, gross oedema, burns, or intolerance to motion.

General Information (Caution) (Warning)

- There are no special skills required to operate the system.
- The Medical Professional is responsible for applying his/her best medical judgment when using the system.
- The electricity supply is of the type indicated on the Power Unit (pump).
- Check the mains lead is free from damage and is positioned so as not to cause an obstruction, or injury. E.g. Strangulation of a child or trip hazard.
- Ensure the mains lead cannot become trapped or crushed, e.g. by raising or lowering of the bed or bed rails or any other moving object.
- The power unit (pump) must only be used with a suitably approved power cord and plug set as supplied by DHS.
- The system is not to be used in the presence of flammable anaesthetics.
- Suitable for continuous use.
- Not suitable for sterilisation.
- Do not position the power unit to make it difficult to disconnect the power supply or plug.
- Do not place the System on or close to a source of heat.
- Do not use with hot water bottles or electric blankets.
- DHS strongly advise against smoking whilst the Power Unit (pump) is in use. This is to prevent accidental secondary ignition of items which may be flammable e.g. bed linen. The materials used in the manufacture of the Suresse mattress comply with the required fire safety regulations.
- Do not use sharp objects on or near the mattress system as this will cause damage.
- Do not store in damp conditions.
- Do not use in an oxygen enriched environment.
- Not suitable for use in an Outdoor Environment.
- Intended for both Home Healthcare and Professional Healthcare environments.
- Do not connect to any other medical device or equipment.
- Correct fuse rating MUST be used. Failure to do so could result in the risk of a fire.
- The System should be cleaned after use or between patients. Refer to Cleaning section.
- All internal and external hoses must be free of twists, kinks. The external hose should also be properly connected and positioned so that the risk of obstruction or injury is eliminated.
- Do not use bleach, phenols. Chlorine based products which exceed 1000ppm. Solvents or alcohol based cleaners.
- All the above warnings and cautions together with safety considerations should be observed at ALL times during its use.
- Select correct pressure 'Hi' or 'Low' as required. Care should be taken not to accidentally change settings once set. This may affect the desired requirement of the therapy. This could also be caused by pets, pests or children.
- This device does not emit radiation.

Detachable/Removable Parts

1. Mattress (Detached from the pump by removing the CPR connector). Part No. MAT/SERESSE/200/85/25 (or variants of for the size)
2. Electric power cable. (Removed from the pump by pulling the cable away from the mains inlet on the side of the pump).

N.B. The battery is an integral part of the Rotor PCB and is not removable or changeable.

Caution

Use of detachable parts not listed is not recommended by Direct Healthcare Services.

Disposal

Please refer to DHS website for recommendations and responsibilities for disposal within the UK WEEE guidelines.

Notes

Notes

Direct Healthcare Services™

Delivering the Promise

ISO 9001:2008
EN ISO 13485:2012

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